UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
	Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Honorable Joel Schneider, Magistrate Judge

WHOLESALER DEFENDANTS' REPLY BRIEF

IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Wholesalers do not belong in this case, and Plaintiffs know it. Claiming only that "there is nothing new or novel about seeking to hold liable entities at the wholesale distribution level of a supply chain[,]" Plaintiffs argue that Wholesalers' unique role does not exempt them from liability. (Plaintiffs' Consolidated Memorandum of Law in Opposition to Defendants' Motions to Dismiss ("Opp.") at 106). Plaintiffs do not, however, provide any facts that would cure Plaintiffs' claims against Wholesalers from their fatal flaws, as described in Wholesalers' Motion to Dismiss. (ECF 522-1).

ARGUMENT[1]

I. WHOLESALERS' UNIQUE ROLE IN THE SUPPLY CHAIN BARS PLAINTIFFS' CLAIMS AGAINST THEM.

Plaintiffs - in an attempt to avoid the reality that Wholesalers' limited role in the supply chain prevents most, if not all, of Plaintiffs' claims against them – cite to inapposite cases that are distinguishable from this case. For example, Plaintiffs repeatedly cite to *Fagan v. AmerisourceBergen Corp.*, where the court declined to dismiss a negligence claim against a wholesaler where the plaintiff alleged that a wholesaler negligently purchased and distributed "prescription drugs in a [sic] such a way as to create or proliferate a 'gray market' that permitted the trade of diverted

[1] Wholesalers adopt and incorporate herein all arguments in Mfrs.' Reply in Support of their Motion to Dismiss ("Mfrs.' Reply"), and Pharmacies' Reply in Support of their Motion to Dismiss ("Pharmacies' Reply").

and counterfeit drugs" bearing allegedly facially defective labels. 356 F. Supp. 2d 198, 209-10, 213 (E.D.N.Y. 2004). In contrast, Wholesalers here simply passed VCDs (with allegedly microscopic contamination) through the standard supply chain from Manufacturers to Pharmacies. Unlike *Fagan*, Plaintiffs here do not include any factual allegations that Wholesalers affirmatively participated in a negligent distribution strategy that created a market for adulterated or facially-obvious misbranded drugs, or even that Wholesalers knew that the VCDs were allegedly misbranded or adulterated. Similarly, *In re Nat'l Prescription Opiate Litigation* (for which Plaintiffs provide an inaccurate citation), a vacated case, discusses duties allegedly owed by wholesalers under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq*. ("CSA"), a statutory framework which has no application to the instant case. *In re Nat'l Prescription Opiate Litigation,* 325 F.Supp.3d 833 (N.D. Ohio 2018) *vacated and remanded,* 927 F.3d 919 (6th Cir. 2019).

The remaining cases, none of which involve pharmaceutical wholesalers, are similarly inapposite and include cases involving sellers to which Wholesalers' role is not comparable. *See Ebin v. Kangadis Family Mgmt LLC*, 45 F. Supp. 3d 395, 397-401 (S.D.N.Y. 2014) (certifying class of consumers where the alleged misconduct arose out of misrepresentations made concerning mislabeled olive oil sold by defendant); *In re Takata Airbags Prods. Liab. Litig.*, No. 15-02599-MD,

2020 WL 2892366 (S.D. Fla. June 1, 2020) (refusing to dismiss consumer class claims against automotive seller who distributed marketing materials about vehicles with purportedly defective airbags manufactured by another company). Finally, in *In re Chinese Manufactured Drywall Prods. Liability Litigation*, the distributor defendants' motion to dismiss did not seek dismissal based on their role in the supply chain, but rather argued that the plaintiffs' recovery should be limited under the economic loss rule. 680 F. Supp. 2d 780, 783 (E.D. La. 2010).

A. Wholesalers are Innocent Sellers Protected From Products Liability Claims, and Plaintiffs Cannot Dispute That.

By virtue of their unique role in the supply chain, Wholesalers here are relieved of liability in those states with Innocent Seller statutes. There are generally three requirements to establish entitlement to dismissal under an Innocent Seller statute: (1) the product's manufacturer must be identified; (2) the Innocent Seller must not have modified, altered, or exerted control over the design, manufacture, or labeling of the product; and (3) the Innocent Seller must not have actual or constructive knowledge of the defect at issue. ECF 522-1 at 6-7.

Plaintiffs do not address the second and third requirements in their briefing, likely because they cannot – they do not allege that Wholesalers modified the product, or any facts that would have put Wholesalers on actual or constructive

notice of contamination in VCDs.[2] Instead, Plaintiffs fixate on the first requirement, arguing that some statutes require the seller to identify the manufacturer, and pointing to a handful of states requiring a seller to submit an affidavit identifying the manufacturer. Opp. at 105-106. This point was precisely addressed in Wholesalers' Motion to Dismiss. ECF 522-1 at 6. Here, the applicable Manufacturers are already parties to this litigation and are subject to the jurisdiction of this Court, and each Plaintiff will be able to conclusively identify the Manufacturer of the VCD he or she purchased and/or consumed through pharmacy records and NDC numbers.[3] Any supposed concern about identifying the VCD Manufacturers is a red herring.

Finally, Plaintiffs argue Wholesalers' Innocent Seller defense fails because Wholesalers did not address every exception to the statutory protection in the charts provided. Opp. at 105-106. Plaintiffs do not point out that it is often the *plaintiff's* burden – not the Innocent Seller's – to establish that one of these statutory exceptions is met. *See, e.g.*, *Gonzalez v. Estes, Inc.*, No. SA-10-CA-0038-XR, 2010 WL

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[2] Plaintiffs do not even address this topic until Page 105 of their Opposition, well beyond their page limit in violation of Local Rule 7.2(d). The Court should thus decline to consider Plaintiffs' argument as to the Innocent Seller defense.

[3] If the Court accepts Plaintiffs' argument that dismissal based on Innocent Seller laws is premature at this time, the issue should be revisited for each individual Plaintiff once the Plaintiff and each respective Pharmacy has completed their fact sheets. The fact sheets will conclusively identify the manufacturer of the VCDs sold to each Plaintiff, at which point there can be no debate that dismissal of Wholesalers based on Innocent Seller laws is ripe.

610778, at *3 (W.D. Tex. Feb. 19, 2010) ("The plaintiff has the burden of proving one of the exceptions to nonliability [in the Texas innocent seller statute]"); *Dakota, Missouri Valley & W. R.R. Inc. v. JMA Rail Prod. Co.*, No. 1:06-CV-02, 2006 WL 2349976, at *2 (D.N.D. Aug. 9, 2006) ("[I]t is clear that the Court shall dismiss the claims against the certifying seller . . . The burden is on the plaintiff to show that [the seller] fits into one of the exceptions and is not merely a passive seller"). Plaintiffs fail to allege that one or more of the exceptions to the statutory protection apply; Plaintiffs' claims must be dismissed against Wholesalers in states with Innocent Seller laws.

B. Plaintiffs Lack Standing to Sue the Entire Supply Chain and Do Not Allege Injury-in-Fact in Relation to Wholesalers.

As discussed in Argument Section I of Mfrs.' Reply, adopted herein, Plaintiffs fail to meet their burden of establishing standing on behalf of the Economic Loss Master Complaint ("ELMC") and Medical Monitoring Master Complaint ("MMMC") Plaintiffs. Additionally, as argued in detail in Wholesalers' Motion to Dismiss, Plaintiffs cannot meet the Article III standing threshold for claims against Wholesalers because they have not alleged facts showing a substantial likelihood that Wholesalers' conduct caused Plaintiffs' harm. *Pub. Interest Research Grp. v. Powell Duffryn Terminals*, 913 F.2d 64, 72 (3d Cir. 1990). Plaintiffs' Opposition admits as much, as its citations to supposed "facts" regarding Wholesalers in the various master Complaints merely cite to vague conclusions. *See, e.g.,* Opp. at 23-

24. These assertions ignore the fact that Wholesalers do not design, formulate, or manufacture VCDs and do not influence or control the manufacturing practices of the API or Finished Dose Manufacturers. Additionally, the existence of Wholesalers' statutory obligations under the DSCSA (1) does not mean Wholesalers violated those obligations, and (2) even if statutory obligations were hypothetically violated, that is still insufficient to confer standing. *See* Mfrs.' Reply Section I.

Furthermore, Plaintiffs fail to show that their alleged harm is "fairly. . . trace[able] to the challenged action." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007). Plaintiffs' Opposition offers a purported quote from *Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000) to argue that an indirect causal relationship is sufficient to fulfill the traceability requirement. **Plaintiffs' purported *Pitt News* quote does not appear anywhere within that opinion.** Plaintiffs' quote is fiction, as is their argument. In fact, *Pitt News* runs contrary to Plaintiffs' argument, and actually supports Wholesalers' argument: Plaintiffs must – but do not – allege that, *but for Wholesalers' conduct*, the alleged contamination would not have occurred, that Plaintiffs would not have purchased and/or consumed allegedly contaminated VCDs, or that Wholesalers' actions were a substantial factor in the alleged contamination or consumption. In *Pitt News*, a newspaper sought to enjoin Act 199, which caused the newspaper's advertisers to withdraw. *Id.* at 357-58. The court held

that, although it was the advertisers that stopped patronizing the newspaper, **Act 199 was the cause-in-fact of the newspaper's injury, because the newspaper's injury was directly traceable to Act 199.** *Id.* at 360-61. There is no allegation here that Wholesalers were the cause-in-fact of Plaintiffs' alleged injuries or that those alleged injuries are directly traceable to Wholesalers' conduct. Thus, Plaintiffs lack standing as to Wholesalers.

Plaintiffs attempt to end-run their Article III standing obligations to prove product identification and traceability as to Wholesalers by proceeding on an alternative and less stringent market share liability theory. Under New Jersey law, it is well-settled that a plaintiff is required to demonstrate product identification, and the market share theory of alternative proof has been expressly rejected in products liability cases. *See, e.g., Namm v. Charles E. Frosst & Co., Inc.*, 178 N.J. Super. 19, 427 A.2d 1121 (App.Div.1981) (plaintiff must prove, as an element of prima facie case, that defendant made the specific product that caused injury); *Gannon v. American Home Products, Inc.*, 211 N.J. 454, 464 (2012) *citing Shackil v. Lederle Laboratories*, 116 N.J. 155, 174, 561 A.2d 511 (1989) (rejecting market share theory as alternative to proof of product identification); *Sholtis v. Am. Cyanamid Co*., 238 N.J. Super. 8, 23, 568 A.2d 1196 (App.Div.1989) (noting the Court's rejection in *Shackil* of market share theory in vaccine context). In fact, when presented with this issue, Courts have declined to expand the law to allow Plaintiffs to allege a market

share theory. *Gianvito v. Premo Pharm. Labs., Inc.,* 93 A.D.3d 546, 547, 940 N.Y.S.2d 272, 273–74 (2012) (applying New Jersey law). Indeed, market share theory is generally disfavored, even with respect to defendants (unlike Wholesalers) who directly participate in the manufacturing process. Plaintiffs here do not cite to any case that applies a market share theory to determine "traceability" for the purposes of standing. Instead, Plaintiffs inaccurately discuss two unrelated and unpersuasive cases that do not advance their theory.

First, Plaintiffs cite *Cottrell v. Alcon Labs., Inc.,* 874 F.3d 154 (3d. Cir. 2017), and state that the "Third Circuit found that the *Cottrell* plaintiffs had established Article III standing to sue on their consumer protection claims against *both* the manufacturers and distributors of eye drop medication." Opp. at 34. Plaintiffs omit the fact, however, that *Cottrell* does not contain any discussion of market share or traceability, neither on appeal in the Third Circuit nor in the District Court (*Cottrell v. Alcon Labs., Inc,* No. 14-5859 (FLW), 2016 WL 1163163 (D.N.J. Mar. 24, 2016)). Defendants' motions to dismiss were based on standing arguments, but did not argue that the product could not be traced back to the distributors. And nothing in the case establishes "a market structure similar to that here," as Plaintiffs misleadingly claim; the two defendant distributors in *Cottrell* were not established to be the only two distributors of that product, or even two of only a few. Moreover, the case indicates the distributors at issue actually *packaged* the eye drops, and the packaging itself

was the crux of the argument in that case. *Cottrell* has no comparison to the litigation at hand where Wholesalers played no such active role.

Next, Plaintiffs discuss *Debernardis v. IQ Formulations, LLC* 942 F.3d 1076 (11th Cir. 2019), which is even less persuasive. Opp. at 34. There were only two defendants in that case – one manufacturer and one distributor. Market share and/or traceability were never discussed in the case because "as the sole distributor that supplied supplements to retailers, ***only [the defendant distributor] could have provided the supplements the plaintiffs bought.***" *Id.* at 1089 (emphasis added). The same cannot be said here. Plaintiffs' Complaint does not allege that Wholesalers are the *sole* distributors of Valsartan, or *the only distributors* who could have provided the VCDs (nor could they successfully argue this). Therefore, Plaintiffs' allegations are not like those in *Debernardis.*

The Court should not permit a market share theory of liability to establish product identification but must instead require Plaintiffs to allege an injury that is fairly traceable to Wholesalers' alleged conduct. Any contrary approach would serve as a "radical departure from the traditional concepts of product liability law," ignore the complexities of the drug supply chain, and potentially lead to absurd results. *See Tidler v. Eli Lilly Co.*, 95 F.R.D. 332, 334 (D.D.C. 1982) (citations omitted).

II. PLAINTIFFS DO NOT OVERCOME PREEMPTION UNDER THE DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) AND/OR PRIMARY JURISDICTION.

Wholesalers adopt and incorporate herein Manufacturers' arguments regarding preemption as articulated in Section II of Mfrs.' Reply. Additionally, Plaintiffs' own case law concedes that dismissal is appropriate where, as here, "preemption is manifest in the complaint itself." *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130–31 (3d Cir. 2018); *see also In re Asbestos Prod. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016).

A. Plaintiffs' Claims Against Wholesalers Are Preempted Under the DSCSA.

Wholesalers adopt in its entirety Pharmacies' Reply Section II discussing preemption. In addition, Plaintiffs falsely suggest that Wholesalers argued that the DSCSA (Drug Supply Chain Security Act, 21 U.S.C. § 360eee-4) preempts *all* of Plaintiffs' claims and that Wholesalers somehow omitted the fact that DSCSA preemption is limited to product tracking/tracing.[4] To the contrary, Wholesalers argued that "Plaintiffs' claims that allege a failure of Wholesalers to adequately ***track or trace*** product through the supply chain are expressly preempted by the

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[4] Additionally, Plaintiffs attack two cases – *Moore v. Johnson & Johnson*, 907 F.Supp.2d 646, 651 (E.D. Pa. 2012) and *Sherfey v. Johnson & Johnson*, No. CIV.A. 12-4162, 2012 WL 3550037, at *1 (Ed. Pa. Aug. 17, 2012) – as having nothing to do with the DSCSA. Plaintiffs fail to note that those cases were neither presented nor relied on in the DSCSA Preemption section of Wholesalers' Motion to Dismiss.

DSCSA and should be dismissed." ECF 522-1 at 10. Regardless, as Plaintiffs agree that the DSCSA preempts claims based on product tracing, Plaintiffs concede Wholesalers' DSCSA argument; any claims premised on Wholesalers' alleged failure to adequately track or trace product through the supply chain should be dismissed as a matter of law.

B. Plaintiffs' Claims Premised on Wholesalers' Alleged Duty to Test Fall Within FDA's Primary Jurisdiction.

Wholesalers adopt in its entirety Mfrs.' Reply Section II discussing primary jurisdiction. In addition, Plaintiffs fail to address Wholesalers' argument that causes of action that rely on the allegation that Wholesalers failed to *test* VCDs for nitrosamines must be dismissed because primary jurisdiction applies. Plaintiffs acknowledge that the doctrine of primary jurisdiction is applicable to particularly complicated issues that Congress has committed to a regulatory agency, and concede that their Complaints raise numerous issues within FDA's specialized expertise. *See* Opp. at 46; ECF 520-3 at 28-29 (listing specialized topics). Plaintiffs do not and cannot reasonably dispute that FDA has the exclusive competency to determine how to conduct testing of drug products for nitrosamines and who should do it. That competency is made apparent in FDA's recent Guidance titled *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry* (September 2020) (available at https://www.fda.gov/media/141720/download) (last accessed October 14, 2020) (Exhibit 1). The Guidance provides numerous detailed recommendations

to API and finished-dose manufacturers about how to test for and detect nitrosamines in drug products, including VCDs. However, the Guidance does not recommend that *Wholesalers* should test for nitrosamines. As such, to the extent Plaintiffs' claims against Wholesalers are premised on an alleged duty to test, the Court should abstain from those claims on primary jurisdiction grounds, or otherwise risk inconsistent rulings on a complicated issue committed to a regulatory agency.

III. PLAINTIFFS' STATE LAW CLAIMS ARE NOT ADEQUATELY PLED.

Any remaining claims Plaintiffs have against Wholesalers are devoid of supportive factual allegations, and their Opposition does nothing to salvage them. As explained in Mfrs.' Reply Background Section I (which Wholesalers adopt herein), the Complaints are "shotgun pleadings" that assert broad, boilerplate theories, largely directed toward all Defendants collectively without distinguishing between Manufacturers, Wholesalers, and Pharmacies.

Plaintiffs are incorrect that "all that Rule 8 requires" is fair notice to Defendants of the claims against them. Opp. at 20. Federal Rule of Civil Procedure 8 also requires adequate notice of "the grounds upon which each claim rests." *Vibe Micro v. Shabanets*, 878 F.3d 1291, 1293-95 (11th Cir. 2018) (dismissing shotgun pleading where "allegations were 'oftentimes not connected to a particular Defendant or set of Defendants, making it impossible to understand who did what . . .'") (citation omitted).

Additionally, Plaintiffs' argument that Defendants impermissibly seek a "piecemeal" dismissal mischaracterizes Defendants' Motion to Dismiss and the applicable law as explained in Mfrs.' Reply at Section IV.A, which Wholesalers adopt herein. The fact remains that Plaintiffs do not state any legal or factual basis for their state law claims against Wholesalers, under any state's law.

A. Plaintiffs Do Not Plead a Legally Viable Unjust Enrichment Claim Against Wholesalers, Nor Do They Plead Facts Supporting Their Unjust Enrichment Damages.

To date, Plaintiffs have argued a legally unsound fiction that unjust enrichment is some all-encompassing mechanism by which any plaintiff can force any defendant to disgorge all of their profits in every garden variety case. This tortured notion of unjust enrichment is simply not the law – nor are unjust enrichment claims in "harmony . . . among the 50 states," as Plaintiffs claim.

To the contrary, as Defendants explained in their various Briefs, unjust enrichment law varies throughout the states in at least three key ways: whether the state requires (1) conferral of a direct benefit by the plaintiff to the defendant, (2) wrongdoing by the defendant, and/or (3) absence (and/or pleading that there is an absence) of an adequate remedy at law.

Plaintiffs once again recite unsupported legal conclusions that Wholesalers accepted money and "in perpetrating and concealing their wrongful acts, they retained this money." Opp. at 71-72. However, Plaintiffs have yet to articulate a

single act by *Wholesalers* to "perpetrate" or "conceal" other than serving as innocent pass-through sellers who passed the product unopened down the supply chain. Plaintiffs' contention that merely occupying this pass-through role – the same role that most states actively protect via Innocent Seller statutes – is a sufficient basis to fulfill the wrongdoing element of certain states' unjust enrichment claims is ludicrous and devoid of any supporting legal citation; Plaintiffs' unjust enrichment claims against Wholesalers should be dismissed as a matter of law in those states. *See* ECF 522-2, Chart 2.

Plaintiffs do not dispute that they have an adequate remedy at law, or that they did not plead the absence of an adequate remedy at law.[5] Thus, both points are conceded, and Plaintiffs' unjust enrichment claims should be dismissed as a matter of law in the states that require an absence (and/or the pleading of an absence) of an adequate remedy at law as a prerequisite to recover under an unjust enrichment theory. *See* ECF 522-2, Charts 4 & 5.

Plaintiffs likewise concede that at least 22 states require the direct benefit element when they list the states they allege do *not* require a direct benefit. Opp. at 74 n. 36. Although Wholesalers disagree with Plaintiffs' legal conclusion about a

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[5] Having conceded that Plaintiffs have an adequate remedy at law and having not pled the absence of an adequate remedy at law, Plaintiffs half-heartedly try to argue that they are entitled to plead multiple claims hypothetically or in the alternative. Critically, Plaintiffs do not – in any of their Complaints – plead multiple claims hypothetically or in the alternative, so this argument is irrelevant.

handful of states' required direct benefit element, even *arguendo,* Plaintiffs' unjust enrichment claims must be dismissed as a matter of law in, at a minimum, the 22 states Plaintiffs acknowledge require a direct benefit. *See* ECF 522-2, Chart 2.

B. Plaintiffs' Opposition Fails to Establish Wholesalers Owe Plaintiffs a Duty to Test.

Plaintiffs effectively concede that Wholesalers have no duty to test the VCDs they distributed, and as such, claims premised upon Wholesalers' alleged "failure to test" must be dismissed. Plaintiffs cite no authority to support the allegation that Wholesalers owed Plaintiffs a duty to test VCDs for the presence of nitrosamines, and also incorrectly claim that Wholesalers cite no authority to support the argument they have no duty to test, despite the fact that *Plaintiffs* bear the legal burden to allege and establish a duty.

Setting aside the issue of burden, Plaintiffs are wrong on both accounts. It is undisputed that the FDCA and DSCSA do not impose any obligation on Wholesalers that would require them to test VCDs for nitrosamines. *See, e.g.,* Exhibit 1. Further, Wholesalers cite multiple authorities demonstrating that there is no duty for a distributor to inspect for latent defects and that there is no state law duty to test a product independent of the design, manufacture, or labeling of the product. *See* ECF 522-1 at 9-10, 17-18 (citations omitted). Plaintiffs do not contest the cited authorities or provide the Court with any contrary authority. Without a duty there can be no negligence, thus all of Plaintiffs' causes of action premised on Wholesalers' alleged

failure to test VCDs must be dismissed.

C. Plaintiffs' Breach of Express and Implied Warranty Claims Fail.

Plaintiffs' allegations regarding breach of express and implied warranties fail to state a claim as to Wholesalers and should be dismissed.

1. Plaintiffs Cannot Allege Privity With Wholesalers.

As explained in Mfrs.' Reply at Section IV.B. (which Wholesalers adopt herein), certain states require privity for Plaintiffs to maintain their breach of express and/or implied warranty claims. *See* ECF 522-2, Charts 6 & 7. Because Plaintiffs cannot allege that privity exists with Wholesalers, they instead argue that some states have exceptions applicable in this case – but most of these purported exceptions only address privity as to Manufacturers, not Wholesalers. *See, e.g.*, Opp. at 60-61 (discussing various privity exceptions to warranty claims against *Manufacturers*). These supposed exceptions to the privity requirement do not impact the requirement as to *Wholesalers*, and therefore Plaintiffs' breach of express and implied warranty claims in certain states fail as a matter of law.[6]

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[6] Plaintiffs' baseless assertion assert that "[w]arranty claims are also viable against Wholesalers based on indemnification agreements alleged to exist, as well as on agency principles of liability" (Opp. at 58) is similarly unpersuasive. Plaintiffs provide no support for their assertion that the existence of contractual indemnification agreements or "agency principles" somehow create express or implied warranty causes of action against Wholesalers and cite only to a single case that actually provides that the express warranty claim against the distributor of the product did *not* have merit. *Geraczynski v. Nat'l R.R. Passenger Corp.*, No. CIV.A. 11-6385 SRC, 2015 WL 4623466, at *3 (D.N.J. July 31, 2015) (Court refrained from

2. Plaintiffs Do Not and Cannot Allege Any Express Affirmation or Promise Made by Wholesalers, Nor That Any Express Promise Formed the Basis of the Bargain.

Plaintiffs again fail to identify any specific representations made by *Wholesalers*, as opposed to Manufacturers or Pharmacies – and instead only allege that they relied on representations in "FDA-approved labeling materials" that accompanied the VCDs. Opp. at 65. Such references to the product labeling do not adequately identify express warranties. *See Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 707 (D.N.J. 2011) (dismissing express warranty claims as not adequately identified where allegedly "Defendants' written warranties expressly stated that the products could be used on the types of pets set forth in the labels and that they were safe for use on that type of pet."). Also, Plaintiffs do not adequately allege express warranties made by Wholesalers, thus no express warranty could form the basis of the bargain, as required by most states. *See* ECF 522-2, Chart 8.

3. Plaintiffs Do Not Allege the Injury Required to Support a Claim of Breach of Implied Warranty.

Plaintiffs neither allege that the VCDs failed to lower their blood pressure, nor make any allegations of impaired functionality of VCDs, as required for breach of implied warranty claims. Plaintiffs claim they have adequately pled claims for

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granting summary judgment on the breach of express warranty claim because the request was raised in a reply brief, "not because of proof indicating that Plaintiff's claim against SAFCO might be meritorious.").

implied warranties based on *Debernardis*, 942 F.3d 1076, an opinion that did not address breach of warranty claims of any kind. Their arguments therefore lack merit, and Plaintiffs' breach of implied warranty claims should be dismissed.

D. Plaintiffs Do Not Plead the Required Elements of Fraud Against Wholesalers With Sufficient Particularity.

Wholesalers adopt the arguments against Plaintiffs' fraud claims in Section IV.F. of Mfrs.' Reply. Plaintiffs concede that knowledge of a statement's falsity is a required element to state a claim for fraud. Opp. at 83-84. Yet not only do Plaintiffs fail to allege Wholesalers' knowledge of the purported defects or any specific misrepresentation or omission made by Wholesalers with sufficient particularity,[7] but also Plaintiffs also fail to plead *any factual allegations* demonstrating with particularity that Plaintiffs *relied* on any alleged misrepresentation or omissions made by Wholesalers. *See Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). Additionally, Plaintiffs do not allege facts demonstrating that Wholesalers owed them a *duty to disclose* information within their control in order to plead fraud by omission.

[7] Plaintiffs' claims for alleged violations of state consumer protections statutes against Wholesalers also are subject to the Fed. R. Civ. P. 9(b) heightened pleading standard applicable to fraud claims, and Plaintiffs do not contend otherwise. As such, Plaintiffs' claims against Wholesalers for alleged violations of consumer protection statutes also must be dismissed.

E. Plaintiffs Do Not Allege Facts to Support Negligent Misrepresentation/Omission Claims Against Wholesalers.

Plaintiffs neither addressed nor responded to Defendants' arguments that Plaintiffs' conclusory and vague negligent misrepresentation claims are inadequate as to Wholesalers, thus conceding the argument. As such, the negligent misrepresentation/omission claims should thus be dismissed.

F. Plaintiffs' Allegations Are Insufficient to Sustain a Claim for Negligence Against Wholesalers.

Plaintiffs' Complaints are devoid of the required allegations that Wholesalers breached a specific duty causing injury to Plaintiffs. Plaintiffs' attempt to remedy that deficiency in their Opposition acknowledges as much. Plaintiffs attempt to now allege Wholesalers had common law duties to "appropriately vet their generic manufacturer suppliers to ensure that they did not sell adulterated, misbranded and/or contaminated product" and "to exercise reasonable care in their acquisition and re-sale of products." Opp. 81, 82. However, **those allegations are not found in Plaintiffs' Complaints, as evidenced by the absence of citations in the Opposition, and Plaintiffs are not permitted to amend their Complaint through statements in briefs.** *See Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d. Cir. 1998) (citations omitted).

G. Plaintiffs Do Not Allege Any Facts in the Personal Injury Complaint That Would Justify Punitive Damages.

Plaintiffs' contention that the Court "should decline to analyze the adequacy

of the allegations underlying the PIMC's request for punitive damages" because it would be improper to do so as a matter of law on a motion to dismiss (Opp. at 94-95) is not supported by the weight of the case law. Courts regularly decide the availability of punitive damages at this stage, and readily dismiss claims for punitive damages where the plaintiff has failed to sufficiently allege facts to support such a claim. *See, e.g.*, *Bannon v. Allstate Ins. Co.*, No. CIV.A. 14-1229 FLW L, 2015 WL 778828, at *6 (D.N.J. Feb. 24, 2015) (dismissing claim for punitive damages where plaintiff did not plead facts showing actual malice, or a wanton and willful disregard of persons who might be harmed); *Onyejekwe v. Uber Techs., Inc.*, No. CV1910196ESMAH, 2020 WL 2832566, at *3 (D.N.J. June 1, 2020) (same); *Lockhart v. Willingboro High Sch.*, 170 F. Supp. 3d 722, 739 (D.N.J. 2015) (same).

Here, Plaintiffs allege no facts specific to Wholesalers that would give rise to a claim for punitive damages, and generic shotgun assertions as to all Defendants (*see, e.g.,* Opp. at 97) are merely unsupported labels of misconduct. "Mere labels of such misconduct, unsupported by factual grounds, are insufficient." *Lockhart*, 170 F. Supp. 3d at 739.

CONCLUSION

WHEREFORE, for the foregoing reasons, as well as those reasons applicable to Wholesalers as outlined in the co-Defendants' Replies, Wholesalers respectfully request the dismissal of all claims against them.

Dated: October 16, 2020

Respectfully submitted,

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